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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,524	11/05/2001	John Doorbar	17746/1074	2747

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EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/008,524

Applicant(s)

DOORBAR, JOHN

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-12 and 14-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-12 and 14-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/314,268.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Claim Rejections - 35 USC § 112***

Claims 1-5, 7-12, 14-64 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an interpreting step which relates binding of the E4-detecting molecule to the detection of a precancerous lesion.

***Claim Rejections - 35 USC § 102***

Claims 1-5, 7, 8, 12, 14-30, 64 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Palefsky et al. See for example Table 1 and Figure 2(a) of Palefsky et al. Applicant argues that Palefsky is scientifically questionable because the author detected E4 in nuclei and others (apparently using different antibodies) detected E4 in cytoplasm. However, the location of E4 is not a limitation of invention as claimed. Applicant also argues that Palefsky does not teach the invention, because they tested tissues already known to be infected. The examiner does not understand this argument, because in teaching the invention applicant himself tested only tissues already known to be infected. See all of the working examples, which follow the statement "The invention will now be described by illustrative examples." If there is a disclosed step which can distinguish over this publication (e.g. a step involving sample choice or sample preparation, or a reagent used, or a sample manipulation step, or an interpretation step), the current claims do not point it out.

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Claims 1-5, 7-12, 14-64 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Doorbar et al. See for example Figures 2, 3, and 4 of Doorbar et al. Applicant argues Doorbar does not teach the invention, because they tested tissues already known to be infected. Again, the examiner does not understand this argument, because in teaching the invention applicant himself tested only tissues already known to be infected. If there is a disclosed step which can distinguish over this publication (e.g. a step involving sample choice or sample preparation, or a reagent used, or a sample manipulation step, or an interpretation step), the current claims do not point it out.

Claims 1-5, 7, 8, 12, 14-30, 64 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5,415,995 (Schoolnik et al). Applicant argues that the patent claim 1 method does not teach the instant method of detecting a precancerous lesion resulting from a mucosal papillomavirus infection. However, Schoolnik provides an antibody specific for parts of HPV16 E4; HPV16 is a mucosal type, regardless of whether or not Schoolnik points out this inherent characteristic. Applicant's claims require contacting a sample from the site of potential infection with the binding molecule; Schoolnik's claims require contacting a clinical sample with the antibody for indicating the presence of human papillomavirus (therefore potential infection is clearly implicit). Applicant's claims require monitoring binding, Schoolnik's claims require detecting an antibody/antigen complex. What is the difference between these claims?

Applicant argues that the patent does not provide any data involving an E4-specific antibody; however, a working example is not require to support a

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patent claim, and applicant has not provided clear and convincing evidence of nonenablement of the patent claims. Again, if there is a disclosed step which can distinguish over this patented method (e.g. a step involving sample choice or sample preparation, or a reagent used, or a sample manipulation step, or an interpretation step), the current claims do not point it out.

Claims 1-5, 7, 8, 12, 14-30, 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Crum et al (Virology 178:238-246). Crum teaches screening a collection of 150 potentially infected samples with an anti-E4 antiserum, and detecting cytoplasmic binding in samples with precancerous lesions. Crum apparently did not know whether or not the samples were infected prior to screening, because nucleic acid detection was done after the immunoscreening, see page 240, column 2. The antiserum was specific for HPV16, which is a mucosal type, and determined the type of HPV to be type 16. Although the reference does not provide an epitope map, it is common for antibodies to be induced to hydrophilic regions of proteins, so there is good reason to believe that the polyclonal antibodies detecting E4 included antibodies which bound within a hydrophilic region. Therefore, the reference meets each and every claim limitation. This rejection is not applied to claims which recite SEQ 4, 167, or 168, as the examiner believes that these sequences lie slightly outside of the E4 region shown by Crum in Figure 1; if this is incorrect, please bring the error to the examiner's attention.

***Double Patenting***

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Claims 1-5, 7-12, 14-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,346,377, for reasons of record. Applicant's intent to file a terminal disclaimer upon indication of allowable claims is noted.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/9/04`

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800-1600**